

**REMARKS**

Reconsideration is requested.

Withdrawal of the restriction requirement is requested along with an further non-final Action on the merits of all the claimed subject matter. A Rule 181 Petition is attached along with the requisite Petition fee. The Commissioner is requested to render a Decision on the attached Rule 181 Petition prior to the Examiner issuing a further Action on the merits in the interest of efficient prosecution.

The attached Rule 181 Petition is being filed to expedite prosecution and consideration of the restriction requirement by the Commissioner and grant of the present Petition prior to the Examiner's issuance of a further Office Action on the merits are requested.

Claims 56-91 are pending.

The Commissioner is requested in the attached Petition to invoke his supervisory authority and have the restriction requirement of March 24, 2003 (Paper No. 22), withdrawn and to instruct the Examiner to allow the pending claims or, at least examine all the pending claims, or alternatively, examine the claims to the extent described in ¶2. of the International Search Report received in the parent PCT application, as further detailed below. The claims are directed, in part, to the subject matter of ¶2. of the International Search Report received in connection with the parent application PCT/EP94/01323.

The parent application, Serial No. 08/362,455, is a 371 U.S. national phase of International Application PCT/EP94/01323. The International Search Report received in

connection with International Application PCT/EP94/01323 was filed in the parent application Serial No. 08/362,455, and should have been available to the Examiner in the parent application Serial No. 08/362,455 (i.e., the present Examiner), and hence available in the present application file. Moreover, as indicated in the Remarks of the Amendment filed June 24, 2003, in the present application, a copy of the relevant portion of the International Search Report was filed with the Amendment. A copy of the undersigned's post card receipt of the filing of June 24, 2003 is attached as evidence of the receipt of the same by the Patent Office on June 24, 2003.<sup>1</sup>

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<sup>1</sup> The Commissioner is urged to appreciate that even if the copy of the noted pages of the International Search Report were not provided with the Amendment filed June 24, 2003, as stated by the Examiner in Paper No. 25, every correspondence filed by the undersigned in this application contains the undersigned's telephone number and prosecution would be expedited if the Examiner and/or other appropriate Patent Office personnel would telephone the undersigned to resolve discrepancies or perceived deficiencies in form.

This has been a persistent frustration in the present application where, for example, the Patent Office initially overlooked the fact that a copy of the inventors' Declaration was filed with the original application papers on August 15, 2000, leading to the issuance of a Notice to file the same on October 12, 2000 and the applicants' response of November 14, 2000, with a further copy of the Declaration.

The undersigned was then contacted by Ms Chadwick of the Patent Office on November 29, 2000 by telephone with a request to file a copy of all the previously- filed papers. The undersigned responded by filing, by Hand Carry, a copy of the requested papers on November 30, 2000.

The Examiner issued an Office Action requiring restriction on December 17, 2001 which the applicants noted in a Response filed January 17, 2002 include an incorrect number of pending claims.

The Examiner then issued a Communication on March 25, 2002 stating that the Response of January 17, 2002 was non-responsive due to the lack of a Sequence Listing and a discrepancy regarding the number of originally-filed claims in the application. The applicants responded May 28, 2002, noting the applicants Request of August 15, 2000 requested that the Patent Office use the computer readable copy of the Sequence Listing from the parent application, and that the paper copy of the Sequence Listing filed August 15, 2000, was the same as the computer readable copy submitted in the parent application. The applicants also requested clarification with regard to the Patent Office copy of the originally-filed claims, a second copy of which was hand carried to Ms Chadwick on November 30, 2000. The undersigned further specifically requested that the Examiner contact the undersigned by telephone to resolve any discrepancy between the Patent Office file and the originally-filed papers.

The Examiner then issued a Communication on July 29, 2002 stating that the "reply" filed May 28, 2002 and the response filed January 17, 2002 were not fully responsive to the "prior" Office Action because of "several confusing issues" relating to the Sequence Listing and the election. See, Paper No. 17.

The undersigned then arranged a personal interview with the Examiner's Supervisor (Examiner Woodward) on August 7, 2002, wherein the undersigned presented the applicants copy of the file for Patent Office inspection and review. It was determined during the personal interview that the "USPTO inserted wrong specification in case. Correct specification will be inserted & amendments processed. No

A further copy of the relevant pages of the Search Report are attached. The attached pages of the Search Report indicate that "No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.: 1,2,6-10 partially; 11, 15-23 partially." Moreover, the attached indicates that during the International Phase of PCT/EP94/01323, there was a determination of lack of unity of invention which included as an alleged separately patentable invention, subject matter described as follows: "2. Claims 1;2;6-10 (partially); 11;15-23 (partially): Polynucleotides or amino acids corresponding to other regions of the genus of HCV subtypes 3, 3a and 3c and their uses."

The pending claims of the present application are directed, at least in part, to "(polynucleotides or) amino acids corresponding to other regions of the genome of HCV subtypes 3, 3a and 3c and their uses" wherein "other regions" refers to regions "other than Core/E1". "Polynucleotides or amino acids corresponding to the core/E1 region of HCV subtype 3a and their uses." defines alleged separately patentable subject matter of ¶1. of the International Search Report (copy attached).

As requested in the Remarks of the Amendment dated June 24, 2003, the applicants request, at a minimum, examination of the subject matter defined by ¶2. of

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response to Paper No. 17 [i.e., the Communication dated July 29, 2002] (07/29/02) is necessary" See, Interview Summary dated August 7, 2002 (Paper No. 18).

The undersigned then filed a further copy of the following on September 13, 2002, via facsimile, in response to a telephonic request for the same from Ms Tracey Johnson of the Patent Office: copy of Amendment and cover sheet filed November 14, 2000 and attached Notice and post card receipt of August 15, 2000; and copy of Preliminary Amendment, IDS and PTO 1449 Form filed August 15, 2000.

The Patent Office presumably had a further complete copy of the application on September 13, 2002, or more than two years after the application was originally and properly filed on August 15, 2000.

The Patent Office is requested to expedite a decision on the attached Petition and, in general, the prosecution of this application.

the International Search Report (copy attached). The applicants believe that the Examiner should at least allow examination in one application of the subject matter defined by the International Phase Unity of Invention because the Examiner has, in the latest restriction requirement of March 24, 2003, based the restriction requirement on the principles of unity of invention, as described under PCT Rule 13.1 and "in accordance with 37 CFR 1.499". See, page 2 of the Office Action dated March 24, 2003 (Paper No. 22). Assuming the Examiner is following the principles of unity of invention, the Examiner should allow examination at least to the extent that the claims read on the subject matter of ¶2. of the International Search Report as the principles of unity of invention have been applied previously by the International Searching Authority and expressed in the attached portion of the International Search Report received in connection with the parent application PCT/EP94/01323.

As noted in the remarks of the Amendment filed June 24, 2003, and repeated herein for convenience, the applicants note that specific exemplified sequences defined by ¶2. of the attached International Search Report received in connection with PCT/EP94/01323, include the following:

SEQ ID NO:2 of region NS5B spanning 2675-2745;  
SEQ ID NO:4 of region NS5B spanning 2675-2745;  
SEQ ID NO:6 of region NS5B spanning 2675-2745;  
SEQ ID NO:8 of region NS5B spanning 2675-2745;  
SEQ ID NO:10 of region NS5B spanning 2675-2745;  
SEQ ID NO:12 of region NS5B spanning 2675-2745;  
SEQ ID NO:30 of region NS3/NS4 spanning 1556-1640;

SEQ ID NO:32 of region NS3/NS4 spanning 1632-1764;

SEQ ID NO:34 of region NS3/NS4 spanning 1632-1764;

SEQ ID NO:36 of region NS3/NS4 spanning 1632-1764;

SEQ ID NO:38 of region NS3/NS4 spanning 1632-1764;

SEQ ID NO:40 of region NS3/NS4 spanning 1632-1764;

SEQ ID NO:150 of region NS5B spanning 2661-2753;

SEQ ID NO:218 of region NS5B spanning 2645-2757; and

SEQ ID NO:223 of region NS3/NS4 spanning 1556-1764.

The nucleic acid sequences encoding the same are similarly disclosed.

The Examiner's restriction requirement should be withdrawn and a new non-final Office Action on the merits of all the claimed subject matter mailed.

The only basis for the restriction requirement stated in the Office Action of March 24, 2003 is an allegation that the claims are drawn to "many thousands of polypeptides sequences and variations of polypeptides sequences and methods of using these sequences to prepare antibodies or in polypeptide binding assays." See, page 2 of Paper No. 22. The Examiner's unsupported assertion should not be sufficient to maintain a restriction requirement.

In response to the applicants request for further support for the restriction requirement in the Law, Rules and/or the MPEP, the Examiner indicated again that the "claims embrace and are drawn to many thousands of polypeptides that do not share a common special technical feature." See, page 2 of Paper No. 25.

The Examiner has criticized the traversal of the restriction requirement in the Amendment of June 24, 2003 for allegedly not arguing "that the claimed polypeptides

share a common special technical feature.” Id. With due respect to the Examiner, this is not true. The applicants discussed at length in the Amendment of June 24, 2003, and as repeated and quoted above, that the claims of the present application are defined, at least in part, by the subject matter of ¶2. of the International Search Report received in connection with PCT/EP94/01323. That is, the claims of the present application are drawn, in part, to polynucleotides or amino acids corresponding to other regions (i.e., other than core/E1) of the genome of HCV subtypes 3, 3a and 3c and their uses. The claims of the present application share a common special technical feature, and as further described below, define over the art cited in the Office Action of September 11, 2003.

Specifically, the Examiner has rejected claims 56, 59, 74 and 76-85, to the extent examined (i.e., presumably to the extent the claims read on the elected single species of SEQ ID NO:36, which was elected with traverse in the Amendment dated June 24, 2003) as allegedly being “clearly anticipated” by Simmonds (WO 93/10239 – 27 May 1993). The application published as WO 93/10239, issued as U.S. Patent No. 5,763,159 (a copy of the first page of which, indicating a § 102(e) dated of July 15, 1994, is attached hereto). As SEQ ID NO:36 of the present application was disclosed in the applicants’ priority application EP.401099.2, filed April 27, 1993, and the Patent Office has indicated that the priority applications have been received from the International Bureau in relation to the parent application Serial No. 08/362,455 (see, attached copy of Notification of Acceptance dated February 10, 1995 received in connection with the parent application Serial No. 08/362,455), WO 93/10239, published May 27, 1993, is not citable against the presently claimed invention. The claims are

patentable over the cited Simmonds document. The Section 102 rejection of the noted claims over Simmonds should be withdrawn.

Moreover, the Examiner has alleged that claims 56, 59, 74 and 76-85 are "clearly anticipated" by Chien et al (U.S. Patent No. 6,416,946). As with the Simmonds reference discussed above, Chien is not citable against the presently claimed invention, at least to the extent the Examiner has apparently examined the claims. Specifically, the undersigned notes that the cited Chien patent is based, indirectly, on an application filed May 10, 1993 such that the undersigned presumes the earliest § 102(e) date relied upon by the Examiner is May 10, 1993. As SEQ ID NO:36 of the present application was disclosed in the applicants' priority application EP.401099.2, filed April 27, 1993, and the Patent Office has indicated that the priority applications have been received from the International Bureau in relation to the parent application Serial No. 08/362,455 (see, attached copy of Notification of Acceptance dated February 10, 1995 received in connection with the parent application Serial No. 08/362,455), the indicated Chien patent, based on an application filed May 10, 1993, is not citable against the presently claimed invention. The claims are patentable over the cited Chien document. The Section 102 rejection of the noted claims over Chien should be withdrawn.

Even if Chien qualified as prior art against the presently claimed invention, Chien would not anticipate the claimed invention. Specifically, the applicants submit that the HCV sequences disclosed by Chien are HCV type 1a (SEQ ID NO:1/Figure 3) or HCV type 2b (SEQ ID NO:2/Figure 4) sequences. The present claims, to the extent they have been examined and/or defined by ¶2 of the earlier-noted International Search Report, are directed to polypeptides or peptides comprising at least one genotype-

specific amino acid<sup>2</sup> relating to HCV type 3 or type 3a. The indicated sequences disclosed by Chein do not describe each and every element of the presently claimed invention. Chein, even if citable prior art, would not anticipate the presently claimed invention.

As the claims are patentable over the cited art, the Examiner has not demonstrated that all of the pending claims do not share a common special technical feature.

The Examiner was requested, in the Amendment filed June 24, 2003, and the Commissioner is requested in the attached, to appreciate that this application was filed August 15, 2000 and it has taken nearly three years to receive a restriction requirement relating to the subject matter of the present claims.

The Examiner stated in response to a similar remark presented in the Amendment of June 24, 2003, that while the "processing delays" were regretted, "it is noted that applicants petitioned for a two month extension of time in order to respond to the requirement for restriction that was mailed on December 17, 2001." See, ¶(e), page 2 of Paper No. 25. In fact, the applicants responded on January 17, 2002 to the Office Action of December 17, 2001, without requiring any extensions. A copy of the undersigned's post card receipt from the January 17, 2002, filing is attached as evidence of receipt of the same by the Patent Office on January 17, 2002. Clarification is requested in the event the undersigned has misunderstood the Examiner's comment in ¶(e) of Paper No. 25 and/or the relevance of the same.

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<sup>2</sup> As further explained below, and contrary to the Examiner's assertions, one of ordinary skill in the art will appreciate the metes and bounds of genotype-specific nucleotides and amino acids. See,

Continued further restriction of the examined claims of this application and the requirement that further applications now be filed to pursue aspects of the presently claimed invention would be an undue burden on the applicants not only due to the delay in the Patent Office in examining the present application but also due to the fact that the applicants believe the subject matter of the present claims has, in many respects, been previously examined and indicated as allowable over the art of record, by the present Examiner.

Specifically, the applicants note that the claims to nucleic acid sequences encoding many of the corresponding protein sequences of the present application were indicated as allowed August 8, 2000 and May 7, 2001 in the parent application Serial No. 08/362,455, by the present Examiner. Specifically, the applicants believe that, with respect to the claims previously indicated as allowable in the parent application Serial No. 08/362,455, claim 56 of the present application would correspond in many respects to claim 24 of the allowed claims of the parent application; claim 58 of the present application would correspond in many respects to claim 41 allowed in the parent application; claim 86 would correspond in many respects to claim 43 allowed in the parent application; claim 59 of the present application would correspond in many respects to claim 44 allowed in the parent application; claims 64, 65 and 66 of the present application would correspond in many respects to claim 48 allowed in the parent application; claim 91 of the present application would correspond in many respects to claim 49 allowed in the parent application; claim 67 of the present

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attached claims of U.S. Patent Nos. 6,548,244; 5,882,852 and 5,514,539, for example, wherein the Patent Office has granted claims reciting the indicated phrase.

application would correspond in many respects to claim 50 allowed in the parent application; claim 69 of the present application would correspond in many respects to claim 51 allowed in the parent application; claim 70 of the present application would correspond in many respects to claim 52 allowed in the parent application; claims 60, 61 and 87 of the present application would correspond in many respects to claims 54, 55, 56, 57, 58, 59, 60 and 61 allowed in the parent application; claim 62 of the present application would correspond in many respects to claims 62, 63, 64, 65, 66, 67 and 68 allowed in the parent application; claims 71 and 72 of the present application would correspond in many respects to claim 69 allowed in the parent application; and claim 73 of the present application would correspond in many respects to claim 70 in the parent application.

Beyond the correspondence of subject matter between the present application and allowed claims in the parent application 08/362,455, the applicants note that multiple sequences were examined and allowed by the present Examiner in one application of the parent application Serial No. 08/362,455. As the present Examiner is believed to have done a complete search, which was not an undue burden on the present Examiner, in the parent application Serial No. 08/362,455, the applicants believe a search of more than a single sequence in the present application would not place an undue burden on the present Examiner in this application.

The Examiner states in the Office action of September 11, 2003 (Paper No. 25) that "The prosecution of Serial No. 08/362,455 is not germane to the requirement for restriction in the instant application." See, ¶(c) of page 2 of Paper No. 25. This comment appears to be contrary to the Commissioner's Decision dated March 19, 2003,

in the assignee's copending application Serial No. 08/836,075, wherein the Commissioner instructed the Examiner (i.e., Examiner Zeman) to withdraw the restriction requirement and examine claims consistent with a previous restriction requirement ("DISCUSSION Applicants argue that all of the claims currently active in the application were prosecuted and allowed by the same examiner in June, 1999. Applicants have amended the claims only to cancel one dependent claim and to remove some of the sequence identifiers from the claims so as to avoid newly submitted prior art. Applicants argue that since all of the claims were previously considered together they should not be divided now. Applicants basically argue that the Office has been inconsistent in prosecution of this application and that the restriction requirement should be withdrawn.... DISCISON Applicants' petition is **GRANTED**. **The restriction requirement of the last Office action is withdrawn. The application will be forwarded to the examiner for consideration of the response filed December 19, 2002.** ... John Doll Director, Technology Center 1600" (emphasis in original)).

Moreover, the applicants submit that the courts have indicated that the prosecution history in parent applications is relevant to the interpretation of the claims of subsequent applications. Further, the actions of the Patent Office should be consistent to promote efficiency of prosecution and to ensure that the applicants and the public can rely on actions taken by the Patent Office in making future decisions. Applicants should not be left to guess what an Examiner's action may be years in the future in a related application where the issues, the Law and Rules remain the same.

In view of all the above, withdrawal of the restriction requirement of March 24, 2003, and the art rejections cited in the Office Action of September 11, 2003, and an

Action on the merits of all the pending claims after a favorable Decision on the attached Rule 181 Petition are requested.

The Section 112, second paragraph rejection of claims 56, 59, 74 and 76-85 is traversed. Reconsideration and withdrawal of the rejection are requested in view of the following comments. The Examiner's comments, listed in alphabetically-enumerated subparagraphs, are similarly addressed as follows:

(a) The claims are not indefinite or vague because they read on more than the Examiner has been willing to examine. One of ordinary skill in the art will appreciate the metes and bounds of the claimed invention even though the claims may read on more than the Examiner has examined.

(b) The recitation of "genotype-specific" nucleotides and/or amino acids are well understood by one of ordinary skill in the art, as well as the Patent Office. See, attached claims of U.S. Patent Nos. 6,548,244; 5,882,852 and 5,514,539, for example, wherein the Patent Office has granted claims reciting the objected-to phrase.

(c) The amino acid positions will be understood by one of ordinary skill in the art who reads the present specification, such as at page 32, last part of the 1<sup>st</sup> paragraph, to refer to amino acid residues by their one letter code with positions in the HCV polyprotein. The Examiner is urged to appreciate that patent specifications are addressed to those of ordinary skill in the art and that which is known or will be appreciated by one of ordinary skill in the art need not be repeated in the claims of specification.

(d) Claim 77 has been amended above to include a "process step" as suggested by the Examiner.

(e) Claim 83 has been amended above to obviate the Examiner's concerns.

(f) Claims 82 and 83 have been amended as suggested by the Examiner's helpful comment.

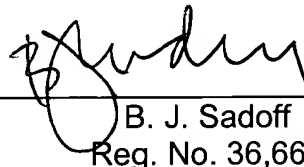
The claims are submitted to be definite and withdrawal of the Section 112, second paragraph rejection of claims 56, 59, 74 and 76-85 is requested.

The claims are submitted to be in condition for allowance. A Notice to that effect is requested after the Commissioner renders a Decision on the attached Rule 181 Petition.

Respectfully submitted,

**NIXON & VANDERHYE P.C.**

By: \_\_\_\_\_

  
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